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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/769,579	01/25/01	DELUCA	H 960296.95700

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EXAMINER	
STILLER,K	
ART UNIT	PAPER NUMBER
1617	5

DATE MAILED: 10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/769,579	Applicant(s) DELUCA ET AL.	
	Examiner Karl Stiller	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over EURODIAB in view of Mathieu et al. (see IDS, Paper No. 4, filed August 6, 2001), Mauricio et al., and DeWille et al. (US 5,817,351).

EURODIAB teaches a method of delaying the onset of diabetes in a human patient, comprising administering an effective amount of a vitamin D compound broadly (see p. 51, summary, column 1, line 15 through column 2, line 2, lines 10-16, p. 52, column 1, lines 8-15, lines 31-33, p. 53, column 1, lines 19-22, p. 54, column 1, lines 6-9).

The primary reference differs from the claimed invention by not particularly specifying the particular vitamin D compounds to be administered, the administration orally or via diet, or the dosage range recited herein (see Claim 2 and Claim 3).

Mathieu et al. teaches a method of delaying the onset of diabetes in the non-obese diabetic (NOD) mouse, which is a well-known animal model for the study of human autoimmune diabetes, comprising the administration of an effective amount of the vitamin D compound, 1,25-dihydroxyvitamin D_3 (see p. 552, column 1, lines 1-4, column 2, lines 1-6, p. 553, column 1, lines 5-8, p. 554, column 2, line 41 through p. 555, column 1, line 3, p. 556, column 1, lines 5-10, line 25 through column 2, line 3, lines 23-26).

Mauricio et al. teaches a method of delaying the onset of diabetes in the NOD mouse, which is a well-known animal model for the study of human autoimmune diabetes, comprising the administration of 1α-hydroxyvitamin D_3 (which is metabolized to 1,25 dihydroxyvitamin D_3) or 0.4mcg/kg/day of the vitamin D analog, MC903 (calcipotriol) (see p. 64, column 1, lines 1-15, lines 25-33, column 2, lines 14-18 lines 26-46).

DeWille et al. discloses the incorporation of vitamin D compounds broadly (e.g., particularly vitamin D_3, vitamin D_2, 1α,25-dihydroxyvitamin D_3, analogs of 1α,25-dihydroxyvitamin D_3, etc.) into beverages for dietary supplementation (see the abstract, column 8, lines 17-24, column 12, table 5 through column 13, table 8).

It would have been obvious at the time the invention was made to modify the primary reference by administering orally or via diet to a human, the particular vitamin D

compounds, 1,25-dihydroxyvitamin D_3, 1α-hydroxyvitamin D_3, or the vitamin D analog, MC903 (calcipotriol), in an amount between 0.005mcg/kg/day to 0.2mcg/kg/day.

One of ordinary skill would have been motivated to employ a particular vitamin D compound encompassed by the claims herein, such as 1,25 dihydroxyvitamin D_3 or vitamin D analog, MC903 (calcipotriol), in the method of EURODIAB with the expectation of similar therapeutic effects because EURODIAB suggests the use of vitamin D compounds broadly for the same purpose and Mathieu et al. teaches the effectiveness of 1,25-dihydroxyvitamin D_3 to delay the onset of diabetes in a well-known animal model of human autoimmune diabetes, and suggests the further use of vitamin D analogs in the same method. Additionally, Mauricio et al. teaches the effectiveness of employing 1α-hydroxyvitamin D_3 (which is metabolized to 1,25 dihydroxyvitamin D_3), or the vitamin D analog, MC903 (calcipotriol) in a method to delay the onset of diabetes in the same animal model. Similar therapeutic efficacy for the compounds of Mathieu and Mauricio in humans would therefore be reasonably expected.

One would have been further motivated to administer a particular vitamin D such as 1,25 dihydroxyvitamin D_3 or vitamin D analog, MC903 (calcipotriol), to a human orally or via diet, in the method of Mauricio et al. with the expectation of similar therapeutic effects because DeWille et al. teaches that vitamin D compounds are well-known to be supplemented orally via the diet.

Additionally, since optimization of result effective variables is considered within the skill of the artisan, it would have been obvious to one skilled in the art at the time the invention was made to employ between 0.005mcg/kg/day to 0.2mcg/kg/day of a vitamin

D compound encompassed by the claims in the methods herein. See *In re Boesch* 205 USPQ 215.

Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Al-Qadreh et al. in view of DeWille et al. (US 5,817,351).

Al-Qadreh et al. teaches a method of reducing the severity of the diabetes symptom, osteopenia, comprising administering 0.05mcg/kg/day of the vitamin D compound, 1α-hydroxyvitamin D_3, to a human diabetes patient (see p. 15, abstract column 1 lines 1-6, line 25 through abstract column 2, line 9, p. 16, column 2, lines 1-2, p. 17, column 1, line 8 through column 2, line 14).

The reference differs from the claimed invention by not expressly teaching the claimed range between 0.005mcg/kg/day to 0.2mcg/kg/day or the administration orally or via diet of the vitamin D compound.

DeWille et al. discloses the incorporation of vitamin D compounds broadly into beverages for dietary supplementation (see the abstract, column 8, lines 17-24, column 12, table 5 through column 13, table 8).

It would have been obvious at the time the invention was made to modify the reference by administering a vitamin D compound orally or via diet in an amount between 0.005mcg/kg/day to 0.2mcg/kg/day.

One would have been further motivated to administer a particular vitamin D to a human orally or via diet in the method of Al-Qadreh et al. with the expectation of similar therapeutic effects because DeWille et al. teaches that vitamin D compounds are well-known to be supplemented orally via the diet.

One of ordinary skill would have further been motivated to employ between 0.005mcg/kg/day to 0.2mcg/kg/day of 1α-hydroxyvitamin D_3 since optimization of result effective variables is considered within the skill of the artisan. See *In re Boesch* 205 USPQ 215.

Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl Stiller whose telephone number is 703-306-3219. The examiner can normally be reached Monday through Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached at 703-308-4612. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Stiller: ks
October 5, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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